

REMARKS

The foregoing amendments and the following comments are responsive to the objections and rejections set forth by the Examiner in the January 31, 2003 Office Action.

Claims 1-18 are pending in this application. The Examiner rejected Claims 1-18. In particular, the Examiner rejected Claims 1, 2, 15, 16, and 17 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,776,237 ("the Hill patent"). The Examiner further rejected Claims 4 and 5 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,776,237 ("the Hill patent"). The Examiner further rejected Claim 6 under 35 U.S.C. § 103(a) as being unpatentable over Hill in view of U.S. Patent No. 6,033,419 ("the Hamblin patent"). The Examiner further rejected Claims 3, 7-14, and 18 under 35 U.S.C. § 103(a) as being unpatentable over Hill in view of U.S. Patent No. 5,403,338 ("the Milo patent"). In view of the following discussion, reconsideration of the application is respectfully requested.

REJECTION OF CLAIMS 1, 2, 15, 16, and 17 UNDER 35 U.S.C. § 102(b)

The Examiner rejected Claims 1, 2, 15, 16, and 17 under 35 U.S.C. § 102(b) as being anticipated by Hill.

Applicant respectfully submits that the claims as previously pending are patentably distinguished over the Hill patent, the other cited references or any combination thereof. Claims 1 and 15, however, have been amended without altering their scope in order to clarify the features of Applicant's inventions. These claim amendments are not made for patentability purposes, and it is believed that the claims would satisfy the statutory requirements for patentability without the entry of such amendments.

Claim 1

Referring to Figures 2 and 3, Hill appears to disclose an apparatus adapted for cutting holes in a blood vessel or comprising a knife edge **21**, an anvil **27**, and a spring

18 to bias the knife edge **21** away from the anvil **27**. The anvil **27** of Hill is larger in diameter than the knife edge **21** and is, therefore a hammer anvil, not a shearing anvil.

Hill does not, however, appear to disclose, teach, or suggest rotation of the knife edge **21** relative to the anvil **27** as it is being advanced toward the anvil **27**.

In contrast, in at least an embodiment of the present invention, the handle **20** provides rotational force to the cutter **12** to assist in tissue penetration. Furthermore, in at least one embodiment of the invention, as shown in Figure 3, the handle **20** and the cutter **12** are rotated until full penetration of the hollow organ has occurred, under force of the spring **22** and the distal edge of the cutter **12** rests against the anvil **16**. In all embodiments of the present invention, the cutter **12** is rotated relative to the anvil **16**, which does not rotate. Furthermore, in all embodiments of the present invention, the anvil **16** is wider in diameter than the cutter **12** and is, therefore, a hammer anvil.

In summary, Hill's surgical punch uses only linear motion between the cutter and the hammer anvil to cut tissue and no rotational motion is provided by Hill. This device results in extremely poor cutting with resultant ragged tissue edges. In contrast, the Applicant's punch uses a rotating motion for the cutter relative to the hammer anvil while cutting the tissue.

Because the Hill reference does not appear to disclose, teach or suggest the use of a rotating cutter relative to his hammer anvil, the Applicant asserts that Claim 1 is not anticipated by Hill. Applicant therefore respectfully submits that Claim 1 is patentably distinguished over the cited reference and Applicant respectfully requests allowance of Claim 1.

Claim 2

Claim 2 which depends from Claim 1, is believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein. In addition, Hill appears to use the spring **18** to bias the knife **21** away from the anvil **27**. In the Hill patent, the force exerted to cause the knife **21** to advance toward the anvil **27** is supplied by manual force on the rod **13** withdrawing it toward the bridge **19**.

In contrast, in at least one embodiment of the present invention, the spring **22** biases the cutter **12** toward the anvil **16** and provides the necessary controlled force to bring the cutter **12** into contact with the anvil **16**. Using the spring **22** to control the force permits a more accurate placement of the device as the user can direct his/her attention at placement only. The spring **22** also prevents too much force being applied, which tears the tissue.

Because the Hill reference does not appear to disclose, teach or suggest the use of a spring to provide a controlled force to move the cutter and the anvil together, the Applicant asserts that Claim 2 is not anticipated by Hill. Applicant therefore respectfully submits that Claim 2 is patentably distinguished over the cited reference and Applicant respectfully requests allowance of Claim 2.

Claim 15

Referring to Figures 2 and 3, Hill appears to disclose an apparatus adapted for cutting holes in a blood vessel or comprising a knife edge **21**, an anvil **27**, and a spring **18** to bias the knife edge **21** away from the anvil **27**. The anvil **27** of Hill is larger in diameter than the knife edge **21** and is, therefore a hammer anvil.

Hill does not, however, appear to disclose, teach, or suggest rotation of the knife edge **21** relative to the anvil **27** as it is being advanced toward the anvil **27**.

In contrast, in at least an embodiment of the present invention, the handle **20** provides rotational force to the cutter **12** to assist in tissue penetration. Furthermore, in at least one embodiment of the invention, as shown in Figure 3, the handle **20** and the cutter **12** are rotated until full penetration of the hollow organ has occurred, under force of the spring **22** and the distal edge of the cutter **12** rests against the anvil **16**. In all embodiments of the present invention, the cutter **12** is rotated relative to the anvil **16**, which does not rotate. Furthermore, in all embodiments of the present invention, the anvil **16** is wider in diameter than the cutter and is, therefore, a hammer anvil.

In summary, Hill's surgical punch uses only linear motion between the cutter and the hammer anvil to cut tissue and no rotational motion is provided by Hill. In contrast, the Applicant's punch uses a rotating motion for the cutter relative to the hammer anvil while cutting the tissue.

Because the Hill reference, does not appear to disclose, teach or suggest the use of a rotating cutter relative to his hammer anvil, the Applicant asserts that Claim 15 is not anticipated by Hill. Applicant therefore respectfully submits that Claim 15 is patentably distinguished over the cited reference and Applicant respectfully requests allowance of Claim 15.

Claims 16 and 17

Claim 16 and 17, which depend from Claim 15, are believed to be patentable for the same reasons articulated above with respect to Claim 15, and because of the additional features recited therein.

REJECTION OF CLAIMS UNDER 35 U.S.C. § 103(a)

The Examiner rejected Claims 4 and 5 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 3,776,237 ("the Hill patent"). In view of the following discussion, Applicant respectfully traverses this rejection.

Claims 4 and 5

Claims 4 and 5, which depend from Claim 1, are believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein.

Claim 6

The Examiner rejected Claim 6 under 35 U.S.C. § 103(a) as being unpatentable over Hill in view of U.S. Patent No. 6,033,419 ("the Hamblin patent").

Claim 6, which depends from Claim 1, is believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein.

Claims 3, 7-14, and 18

The Examiner rejected Claims 3, 7-14, and 18 under 35 U.S.C. § 103(a) as being unpatentable over Hill in view of U.S. Patent No. 5,403,338 ("the Milo patent").

Claim 7

Claim 7 has been canceled and the elements of Claim 7 have been added to Claim 1 by way of amendment. The foregoing discussion, therefore, is directed toward Claim 1.

The Milo patent appears to disclose a punch for opening a passage between two compartments comprising an outer hollow tube with a sharp distal edge constituting a circular knife. The Milo punch also appears to comprise an inner needle tube with a proximal end and a beveled distal end. The Milo punch appears to comprise an anvil 7 that is smaller in diameter than the circular knife 9. Threads 6 on the distal end of the anvil 7 are rotated by a screw-actuating member 3 on the proximal end of the inner needle tube 2.

The Milo Patent does not appear to disclose or teach rotation of the circular knife 9 relative to the anvil 7 during the cutting operation. Referring to Figures 1 and 2, rotation of the anvil 7 is performed to screw the anvil 7 into and through tissue. Referring to Figure 2, the outlet 4 passes through the outer tube so as to prevent any rotation of the circular knife 9 relative to the anvil. Any rotation is intended only to screw the distal end of the inner needle tube 2 into tissue so as to widen the tissue. No mention is made in the patent of rotating the circular knife 9 while performing the cutting operation. Furthermore, the non-circular cross-section shown in Figure 5 prevents the circular knife 9 from rotating as it passes around the anvil 7. Thus, the combination of Hill and Milo do not anticipate the use of a controlled force to advance a cutter or circular knife against a hammer anvil while the cutter is being rotated relative to the hammer anvil.

In summary, there is no suggestion to combine the functions of a hammer anvil with rotation during cutting and a controlled force to perform the cutting in Hill or Milo.

Because the references cited by the Examiner do not disclose, teach or suggest the use of a hammer anvil, a rotating cutter, and a controlled cutting force, Applicant

asserts that Claim 1 is not obvious in view of Hill and Milo, alone or in combination. Applicant therefore respectfully submits that Claim 1 is patentably distinguished over the cited references and Applicant respectfully requests allowance of Claim 1.

The Hill and Milo references fail to disclose a hammer anvil, a rotating cutter, and a controlled cutting force, for the purpose of punching holes in hollow organs or vessels. The Examiner asserts that it would have been obvious to rotate the cutter relative to the anvil in combination with the Hill reference. The Examiner, however, has not established that the ordinary knowledge of those skilled in the art would have used the Hill reference to build a punch using a hammer anvil, a controlled force, and rotation of the cutter during cutting. Furthermore, the Examiner has not established that one of ordinary knowledge would have then combined Hill and Milo to create the invention of the present patent.

Applicant therefore respectfully submits that Claim 1 is patentably distinguished over the cited references and Applicant respectfully requests allowance of Claim 1.

Claim 3

Claim 3 of the present invention discloses a controlled force on the cutting blade generated by a jackscrew with a manual knob for advancement of the cutting blade. The examiner asserts that the Milo patent discloses, in Figure 1, a cutting blade 9 being generated by a jackscrew with a knob 3 for manual and rotational advancement of the cutting blade toward the anvil.

The Milo patent, however, appears to disclose a knob for rotating the anvil 7 (which is called a cutting disc 7) into tissue. This cutting disc 7 is not the same as the cutting blade 9, but appears to be an anvil. The Milo patent has a screw structure 6 that is threaded into tissue. This is not the same as a jackscrew used to move the cutting blade 9 toward the anvil 7.

Thus, the combination of Hill and Milo do not anticipate the use of a manually operated jackscrew to advance a cutter or circular knife against a hammer anvil while the cutter is being rotated relative to the hammer anvil.

Furthermore, Claim 3, which depends from Claim 1, is believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein.

Claims 8-12

Claim 8, 9, 10, 11, and 12, which depend from Claim 1, are believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein.

Claim 13

Claim 14 has been cancelled and the elements of Claim 14 have been incorporated into Claim 13. The foregoing discussion, therefore, is directed toward amended Claim 13.

The Milo patent appears to disclose a punch for opening a passage between two compartments comprising an outer hollow tube with a sharp distal edge constituting a circular knife. The Milo punch also appears to comprise an inner needle tube with a proximal end and a beveled distal end. The Milo punch appears to comprise an anvil 7 that is smaller in diameter than the circular knife 9. Threads 6 on the distal end of the anvil 7 are rotated by a screw-actuating member 3 on the proximal end of the inner needle tube 2.

The Milo Patent does not appear to disclose or teach rotation of the circular knife 9 relative to the anvil 7 during the cutting operation. Referring to Figures 1 and 2, rotation of the anvil 7 is performed to screw the anvil 7 into and through tissue. Referring to Figure 2, the outlet 4 passes through the outer tube so as to prevent any rotation of the circular knife 9 relative to the anvil. Any rotation is intended only to screw the distal end of the inner needle tube 2 into tissue so as to widen the tissue. No mention is made in the patent of rotating the circular knife 9 while performing the cutting operation. Furthermore, the non-circular cross-section shown in Figure 5 prevents the circular knife 9 from rotating as it passes around the anvil 7. Thus, the combination of Hill and Milo do not anticipate the use of a controlled force to advance a cutter or

circular knife against a hammer anvil while the cutter is being rotated relative to the hammer anvil.

In summary, there is no suggestion to combine the method of using a hammer anvil with rotation during cutting and a controlled force to perform the cutting in Hill or Milo.

The Hill and Milo references fail to disclose a hammer anvil, a rotating cutter, and a controlled cutting force, for the purpose of punching holes in hollow organs or vessels. The Examiner asserts that it would have been obvious to rotate the cutter relative to the anvil in combination with the Hill reference. The Examiner, however, has not established that the ordinary knowledge of those skilled in the art would have used the Hill reference to build a punch using a hammer anvil, a controlled force and rotation of the cutter during cutting. Furthermore, the Examiner has not established that one of ordinary knowledge would have then combined Hill and Milo to create the invention of the present patent.

Because the references cited by the Examiner do not disclose, teach or suggest using a hammer anvil, a rotating cutter, and a controlled cutting force, Applicant asserts that Claim 13 is not obvious in view of Hill and Milo, alone or in combination. Applicant therefore respectfully submits that Claim 13 is patentably distinguished over the cited references and Applicant respectfully requests allowance of Claim 13.

Claim 18

Claim 18 has been cancelled and the elements of Claim 18 have been incorporated into Claim 15. The foregoing discussion, therefore, is directed toward amended Claim 15.

The Milo patent appears to disclose a punch for opening a passage between two compartments comprising an outer hollow tube with a sharp distal edge constituting a circular knife. The Milo punch also appears to comprise an inner needle tube with a proximal end and a beveled distal end. The Milo punch appears to comprise an anvil 7 that is smaller in diameter than the circular knife 9. Threads 6 on the distal end of the anvil 7 are rotated by a screw-actuating member 3 on the proximal end of the inner needle tube 2.

The Milo Patent does not appear to disclose or teach rotation of the circular knife 9 relative to the anvil 7 during the cutting operation. Referring to Figures 1 and 2, rotation of the anvil 7 is performed to screw the anvil 7 into and through tissue. Referring to Figure 2, the outlet 4 passes through the outer tube so as to prevent any rotation of the circular knife 9 relative to the anvil. Any rotation is intended only to screw the distal end of the inner needle tube 2 into tissue so as to widen the tissue. No mention is made in the patent of rotating the circular knife 9 while performing the cutting operation. Furthermore, the non-circular cross-section shown in Figure 5 prevents the circular knife 9 from rotating as it passes around the anvil 7. Thus, the combination of Hill and Milo do not anticipate the use of a controlled force to advance a cutter or circular knife against a hammer anvil while the cutter is being rotated relative to the hammer anvil.

In summary, there is no suggestion to combine the method of using a hammer anvil with rotation during cutting and a controlled force to perform the cutting in Hill or Milo.

The Hill and Milo references fail to disclose a hammer anvil, a rotating cutter, and a controlled cutting force, for the purpose of punching holes in hollow organs or vessels. The Examiner asserts that it would have been obvious to rotate the cutter relative to the anvil in combination with the Hill reference. The Examiner, however, has not established that the ordinary knowledge of those skilled in the art would have used the Hill reference to build a punch using a hammer anvil, a controlled force and rotation of the cutter during cutting. Furthermore, the Examiner has not established that one of ordinary knowledge would have then combined Hill and Milo to create the invention of the present patent.

Because the references cited by the Examiner do not disclose, teach or suggest using a hammer anvil, a rotating cutter, and a controlled cutting force, Applicant asserts that Claim 15 is not obvious in view of Hill and Milo, alone or in combination. Applicant therefore respectfully submits that Claim 15 is patentably distinguished over the cited references and Applicant respectfully requests allowance of Claim 15.

Claims 16 and 17

Claims 16 and 17, which depend from Claim 15, are believed to be patentable for the same reasons articulated above with respect to Claim 15, and because of the additional features recited therein.

AFFIDAVIT

The Applicant has enclosed a letter from Dr. Richard Wampler, a local surgeon, which outlines his opinion regarding the performance of my punch compared to the state-of-the art devices.

CONCLUSION

In view of the forgoing, the present application is believed to be in condition for allowance, and such allowance is respectfully requested. If further issues remain to be resolved, the Examiner is cordially invited to contact the undersigned such that any remaining issues may be promptly resolved.

Respectfully submitted,

Dated: 4-29-03

By: Eugene M. Breznock
Eugene M. Breznock



Richard Wampler, M.D.
5360 Barton Road
Loomis, CA 95650

RECEIVED

MAY 19 2003

April 28, 2003

TECHNOLOGY CENTER R3700

To Whom It May Concern:

I have been asked by Eugene Breznock DVM to comment on his invention as described in his patent application number (09/938,428). Information on Dr. Breznock's invention has been confidentially shown to me and I have reviewed his patent application, and examined and used a prototype.

I am a licensed physician in the State of California, trained in general surgery. Since 1981 I have been involved in the research, development and testing of artificial hearts, including the surgical placement of such devices. In addition, I was a member of the open-heart surgery team at Mercy General Hospital in Sacramento where I was a surgical assistant in numerous cardiac surgical procedures. In these roles, I have had many occasions to observe and use hole punch devices intended to perform the functions proposed for Dr. Breznock's invention.

The devices now commercially available, such as the Hancock and Medtronic Punch, work as cylindrical scissors and, in my experience often result in 1) tearing of tissue and produce ragged margins, 2) unpredictable hole size and 3) limited visibility which compromises the accuracy of hole placement. The prototype, which I used, produced a superior result in every regard compared to existing devices. The superior results are surprising to me since a non-rotating hammer anvil and cutter do such a terrible job of cutting soft tissue. The unexpected superior result is attributable to the combined hammer anvil, low controlled spring force, and rotating cutting action of Dr. Breznock's invention. I believe that Dr. Breznock's invention is novel and would offer distinct advantages over the prior art.

Respectfully,

Richard Wampler, M.D.

Version With Markings to Show Changes Made

Please amend the claims as follows:

1. (Currently Amended) An apparatus adapted for cutting holes in a body vessel or hollow organ comprising:

a cutting blade,

a controlled force to advance the cutting blade, and

an anvil having a proximal surface against which the cutting blade is advanced wherein the cutting blade does not pass beyond the proximal surface of the anvil,

wherein the cutting blade rotates relative to the anvil while the cutting blade is being advanced toward the anvil.

13. (Currently Amended) A method for creating a hole in a hollow organ or body vessel comprising the steps of:

creating an incision in said hollow organ or body vessel with a sharp object,

advancing a tapered trocar through said hollow organ or body vessel at the incision site until the trocar point has completely penetrated said hollow organ or body vessel,

locating a cutting blade coaxially disposed about said trocar so that said cutting blade is positioned correctly,

advancing said cutting blade into said hollow organ or body vessel under controlled force until said cutting blade fully rests against a blunt surface or anvil whose outside diameter is no less than the outer diameter of said cutting blade, and

removing said cutting blade and excised tissue from the hollow organ or body vessel, and

rotating the cutting blade while said cutting blade is being advanced toward said anvil.

15. (Currently Amended) An apparatus adapted for cutting holes in a body vessel or hollow organ comprising:

an anvil,

a cutting blade against which the anvil is advanced wherein the anvil positively stops against the cutting blade, and

a controlled force to advance the anvil,

wherein the cutting blade rotates relative to the anvil while the anvil is being advanced toward the cutting blade.

16. (Currently Amended) The apparatus of claim 15 wherein said controlled force is generated by a jackscrew to move~~manual withdrawal~~ of the anvil against the cutting blade.

17. (Currently Amended) The apparatus of claim 15 wherein said controlled force is generated by a spring biased to move the anvil toward~~is spring loaded in a position separated from~~ said cutting blade.